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EXAMINER	
PRONE, CHRISTOPHER D	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Supp. **Notice of Allowability**	Application No. 09/753,448	Applicant(s) SHELSO, SUSAN I.	
	Examiner Christopher D. Prone	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *An Interview on 1/22/07*.

2. ☒ The allowed claim(s) is/are *1-13,15-21,23-34,36-41 and 43-51*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *11/29/06* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

CDP

SUPPLIMENTAL EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dinesh Melwani on 1/22/07.

The application has been amended as follows:

The claims will be replaced by the following list of claims.

1. A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including

a tubular member including a first marker band at a position corresponding to a distal most leading end of the self-expanding stent to indicate a position of the distal most leading end, a second marker band at a position corresponding to a trailing end of the self-expanding stent to indicate a position of the trailing end, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent, and

an outer member positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction;

a holding sleeve positioned about the tubular member and configured to retain the positioning of the stent, wherein the holding sleeve is positioned within an interior of the stent; and

an inflatable device positioned about the tubular member, wherein there is no more than one inflatable device, wherein said inflatable device is disposed solely between the holding sleeve and the distal end of the catheter, and wherein at least a portion of the self-expanding stent overlaps a portion of the inflatable device prior to deployment of the self-expanding stent.

2. The combination of claim 29, wherein the catheter includes an outer member coaxially positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction.

3. The delivery system of claim 1, wherein the outer member is configured to retain a self-expanding stent in a radially-compressed position and to release the self-expanding stent to a radially-expanded position.

4. The delivery system of claim 3, wherein the inflatable device is a balloon configured to selectively assist the self-expanding stent with radial expansion.

5. A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including

a tubular member including a first marker band at a position corresponding to a distal most leading end of the self-expanding stent, a second marker band at a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands, and

an outer member positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction;

a holding sleeve positioned about the tubular member and configured to retain the stent, wherein the holding sleeve is positioned within an interior of the stent;

an inflatable device positioned about the tubular member, wherein there is no more than one inflatable device,. wherein said inflatable device disposed solely between the holding sleeve and the distal end of the catheter; and

a loading funnel, the loading funnel being configured to be removably attachable to a distal end of the tubular member and to receive the stent therein as the stent is loaded onto the delivery system.

6. The delivery system of claim 5, wherein the loading funnel is configured to assist with radial compression of the self-expanding stent and advancement of the self-expanding stent within the outer member.

7. The delivery system of claim 1, further comprising a spacing jacket coaxially positioned about the tubular member and inside the outer member.

8. The delivery system of claim 1, further comprising a fluid port, the fluid port configured to receive a fluid and direct the fluid to a region between the tubular member and outer member.

9. The delivery system of claim 1, wherein the distal end of the tubular member includes a tapered tip.

10. The delivery system of claim 9, wherein the tapered tip includes a surface extending radially outward from the tubular member to form a seat to receive the outer member.

11. The delivery system of claim 1, wherein the third marker band indicates a position corresponding to a re-constrain limit of a partially- expanded, self-expanding stent.

12. The delivery system of claim 1, wherein the tubular member defines a first lumen and a second lumen, one of the first lumen and the second lumen configured to receive a guidewire, and the other of the first lumen and the second lumen providing a fluid passage to the inflatable device.

13. The delivery system of claim 1, wherein at least one of the first, second, and third marker bands is a radiopaque marker band.

14. (Cancelled)

15. The delivery system of claim 1, wherein the inflatable device is a balloon.

16. In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

the delivery system of claim 1; and

a self-expanding stent mounted on the delivery system.

17. A method for implantation of a self-expanding stent, the method comprising:

attaching a funnel to a distal end of a delivery system, the delivery system including a catheter having a distal end and being configured to retain a self-expanding stent proximate the distal end, the catheter including a first marker band at a position corresponding to a distal most leading end of the self-expanding stent, a second marker band at a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands, a holding sleeve configured to retain the stent, and an inflatable device provided on the catheter and positioned

beneath at least a portion of the self-expanding stent prior to deployment of the self-expanding stent, wherein there is no more than one inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter, and wherein the holding sleeve is positioned within an interior of the stent;

loading a self-expanding stent onto the delivery system through the funnel;

delivering the delivery system to a region of a vessel to be repaired;

implanting the self-expanding stent into a wall of the vessel to be repaired; and

inflating the inflatable device to assist expansion of the self-expanding stent.

18. The method of claim 17, wherein delivering the delivery system includes:

positioning a medical guidewire; and

guiding the delivery system with the guidewire to the area of the vessel to be repaired.

19. The method of claim 17, wherein delivering the delivery system includes:

positioning an endoscope; and

guiding the delivery system through an endoscope to the area of the vessel to be repaired.

20. The method of claim 17, wherein providing a delivery system includes providing the catheter with a tubular member and an outer member coaxially positioned

about the tubular member, the outer member being slidable relative to the tubular member in an axial direction.

21. The method of claim 20, wherein implanting the self-expanding stent includes effectuating relative axial movement between the tubular member and outer member to release the stent and allow the stent to self-expand.

22. (Cancelled)

23. The method of claim 17, wherein inflating the inflatable device includes re-positioning the already-delivered delivery system such that the inflatable device is properly aligned with the self-expanded stent.

24. The method of claim 23, wherein re-positioning the already-delivered delivery system includes slightly retracting the delivery system from the point of implantation of the stent.

25. The method of claim 17, wherein inflating the inflatable device includes supplying fluid to the inflatable device.

26. The method of claim 25, wherein supplying fluid includes supplying air.

27. The method of claim 25, wherein supplying fluid includes supplying fluid by way of a lumen tube extending through the catheter.

28. The method of claim 17, further comprising:

deflating the inflatable device; and

withdrawing the delivery system from a patient's anatomy.

29. In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

a self-expanding stent;

a catheter having a distal end, the catheter being configured to retain the self-expanding stent proximate the distal end, the catheter including a tubular member having a first marker band at a position corresponding to a distal most leading end of the self-expanding stent to indicate a position of the distal most leading end, a second marker band at a position corresponding to a trailing end of the self-expanding stent to indicate a position of the trailing end, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent;

a holding sleeve positioned about the tubular member and configured to retain the stent, wherein the holding sleeve is positioned within an interior of the stent; and

an inflatable device positioned about the tubular member, wherein there is no more than one inflatable device, at least a portion of the self-expanding stent overlapping at least a portion of the inflatable device prior to deployment of the self-

expanding stent, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter.

30. The combination of claim 2, wherein the outer member is configured to retain the self-expanding stent in a radially-compressed position and to release the self-expanding stent to a radially-expanded position.

31. In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

a self-expanding stent;

a catheter having a distal end, the catheter being configured to retain the self-expanding stent proximate the distal end, the catheter including

a tubular member including a first marker band at a position corresponding to a distal most leading end of the self-expanding stent, a second marker band at a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands, and

an outer member coaxially positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction;

a holding sleeve positioned about the tubular member and configured to retain the stent, wherein the holding sleeve is positioned within an interior of the stent;

an inflatable device provided on the catheter, wherein there is no more than one inflatable device, at least a portion of the self-expanding stent overlapping at least a

portion of the inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter; and

a loading funnel, the loading funnel being configured to be removably attachable to a distal end of the tubular member and to receive the stent therein as the stent is loaded onto the delivery system.

32. The combination of claim 2, further comprising a spacing jacket coaxially positioned about the tubular member and inside the outer member.

33. The combination of claim 2, wherein the third marker band indicates a position corresponding to a re-constrain limit of the self-expanding stent when in a partially-expanded state.

34. The combination of claim 2, wherein the tubular member defines a first lumen and a second lumen, one of the first lumen and the second lumen configured to receive a guidewire, and the other of the first lumen and the second lumen providing a fluid passage to the inflatable device.

35. (Cancelled)

36. A delivery system for a self-expanding stent, the delivery system comprising:

a catheter having a distal end, the catheter being configured to retain a self-expanding stent proximate the distal end, the catheter including a first marker band at a position corresponding to a distal most leading end of the self-expanding stent, a second marker band at a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands;

a holding sleeve positioned about the tubular member and configured to retain the stent, wherein the holding sleeve is positioned within an interior of the stent;

an inflatable device provided on the catheter and positioned proximate the distal end, wherein there is no more than one inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter; and

a loading funnel configured to be removably attachable to the distal end of the catheter and to receive the stent therein as the stent is loaded onto the delivery system.

37. The delivery system of claim 36, wherein the catheter includes a tubular member and an outer member positioned about the tubular member, the outer member being slidable relative to the tubular member in an axial direction.

38. The delivery system of claim 37, wherein the loading funnel is configured to assist with radial compression of the self-expanding stent and advancement of the self-expanding stent within the outer member.

39. The delivery system of claim 37, further comprising a spacing jacket coaxially positioned about the tubular member and inside the outer member.

40. The delivery system of claim 37, wherein the tubular member includes the first marker band, the second marker band, and the third marker band, wherein the third marker band indicates a position corresponding to a re-constrain limit of a partially-expanded, self-expanding stent.

41. The delivery system of claim 37, wherein the tubular member defines a first lumen and a second lumen, one of the first lumen and the second lumen configured to receive a guidewire, and the other of the first lumen and the second lumen providing a fluid passage to the inflatable device.

42. (Cancelled)

43. In combination, a self-expanding stent and a delivery system for the self-expanding stent, the combination comprising:

the delivery system of claim 36; and

a self-expanding stent mounted on the delivery system.

44. A method for implantation of a self-expanding stent, the method comprising:

providing a delivery system including a self-expanding stent, a catheter having a distal end and being configured to retain the self-expanding stent proximate the distal end and including a tubular member having a first marker band at a position corresponding to a distal most leading end of the self-expanding stent to indicate a position of the distal most leading end, a second marker band at a position corresponding to a trailing end of the self-expanding stent to indicate a position of the trailing end, and a third marker band between the first and second marker bands and between the leading and trailing ends of the stent, a holding sleeve positioned about the tubular member and configured to retain the stent, and an inflatable device provided on the catheter and positioned beneath at least a portion of the self-expanding stent prior to deployment of the self-expanding stent, wherein there is no more than one inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter, and wherein the holding sleeve is positioned within an interior of the stent;

delivering the delivery system to a region of a vessel to be repaired;

releasing a portion of the self-expanding stent to a position corresponding with the third marker band on the catheter;

re-constraining the self-expanding stent;

implanting the self-expanding stent into a wall of the vessel to be repaired; and

inflating the inflatable device to assist expansion of the self-expanding stent.

45. The delivery system of claim 1, wherein the holding sleeve is spaced apart from the inflatable device.

46. The delivery system of claim 5, wherein the holding sleeve is spaced apart from the inflatable device.

47. The method of claim 17, wherein the holding sleeve is spaced apart from the inflatable device.

48. The combination of claim 29, wherein the holding sleeve is spaced apart from the inflatable device.

49. The combination of claim 31, wherein the holding sleeve is spaced apart from the inflatable device.

50. The delivery system of claim 36, wherein the holding sleeve is spaced apart from the inflatable device.

51. The method of claim 44, wherein the holding sleeve is spaced apart from the inflatable device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
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